

System Level Manual

Regulatory Standards Division, AMA-200

Document # WI 214.03

Revision Original

Title:

Product Development Plan Execution Work Instruction

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REVISION HISTORY					
Rev	Description of Change	Author	Effective Date		
Α	Original	JLA	06/24/2003		
1	Renumber	JLA	01/22/2004		
2	Update Hyperlinks	DAW	06/09/2006		

REFERENCE DOCUMENTS					
Document Number	Document Title				
QMS 200	AMA-200 Quality Systems Manual				
QP 214	Product Development Procedure				

Documents referenced in this work instruction are applicable to the extent specified herein.

1. Purpose

This work instruction describes the execution process of the approved plan for the design and deployment of a customer requested project.

2. Scope

This work instruction applies to the plan execution stage of the Product Realization Procedure.

3. Definitions and Acronyms

There are no unique definitions or acronyms related to this document.

4. Flowchart

There is no flowchart required for this document.

5. Responsibilities

- 5.1 The **Project Coordinator** (PC) is responsible for the execution of the plan and shall:
 - 5.1.1 Ensure conformance to the plan
 - 5.1.2 Communicate all status reports on a timely basis
 - 5.1.3 Incorporate all approved changes to the plan
 - 5.1.4 Be responsible for the timely completion of the plan



5.2 Project team members shall assist the Project Coordinator.

6. Work Instructions

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6.1	Execute	tne	blan

- 6.1.1 The PC will brief the project team members on the details of the plan
- 6.1.2 Implement the methodology delineated in the plan, i.e. Academy Guidelines
- 6.1.3 The PC will ensure verification of the product
 - 6.1.3.1 Recognized deficiencies will be returned to the point of nonconformance
- 6.1.4 The PC shall ensure validation of the product, if required in the plan
 - 6.1.4.1 Any deficiencies identified are returned to the point of nonconformance.

6.2 Finalization

- 6.2.1 The PC shall ensure finalization of the product including:
 - 6.2.1.1 A completed Customer Product Acceptance Form with any concessions/exceptions noted.
 - 6.2.1.2 Resolution of any deficiencies identified during delivery.
 - 6.2.1.3 Written justification in the event of customer rejection.
 - 6.2.1.4 Initiate the Post Delivery Process Review.
- 6.2.2 The PC shall assemble the Final Report, including:
 - 6.2.2.1 Customer Request Information Document
 - 6.2.2.2 Evaluation of a Customer Request
 - 6.2.2.3 Project Overview Statement
 - 6.2.2.4 The Plan
 - 6.2.2.5 Correspondence, including internal, customer, and contractor
 - 6.2.2.6 Plan Change Request(s), if applicable
 - 6.2.2.7 Verification and validation results
 - 6.2.2.8 Copy of the Product

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6.2.2.9 Customer Product Acceptance Form

7. Metrics

There are no metrics required for this document.

8. Quality Records

Quality Records for this document are listed in the table below. These records shall be generated and managed in accordance with AMA-200 Quality Records procedures.

Verifying Document Type or Number	Title	Retention Time
QF 214.04	Plan Change Request (PCR)	Five Years
QF 214	Customer Request Information Document	Five Years

Quality forms are found in Appendix 1 of the AMA-200 QMS.